AUG 3 0 2000

510(K) SUMMARY

Submitted By:
Brenda Davis
Regulatory Affairs
Cook Urological, Incorporated and Cook OB/GYN™
1100 West Morgan Street
Spencer, Indiana, 47460
(812) 829-4891
August 21, 2000

Device:

Trade Name:	SPECTRUM™ Silicone Foley Catheter
Common/Usual Name:	Urological Catheter, Foley Catheter
Proposed Classification:	Urological Catheter 21 CFR Part 876.5130 (78MJC) Class II

Intended Use:

The SPECTRUM™ Silicone Foley Catheter is a urological catheter indicated for use in urinary tract drainage or urine collection. Urinary tract access is generally accomplished by insertion of the catheter through the urethra and into the bladder, but may also be accomplished by suprapubic placement or by nephrostomy. The device will be supplied sterile and is intended for one-time use.

Predicate Devices:

The SPECTRUM™ Silicone Foley Catheter is comparable in terms of intended use and technological characteristics to predicate silicone Foley catheters including the Cook Urological Silicone Foley Catheter, C.R. Bard's Bardex® Lubri-Sil™ I.C. Foley Catheter and Rochester Medical Corporation's Silicone Antimicrobial Foley Catheter. Like the Cook SPECTRUM/ABRM Catheter for intravascular use, the SPECTRUM™ Silicone Foley Catheter has an antimicrobial coating comprised of a combination of minocycline and rifampin.

Device Description:

The SPECTRUM™ Silicone Foley Catheter is a bilumen 20 Fr catheter with a 5 cc retention balloon. A bifurcated Y-fitting provides access to the funnel drainage lumen and the balloon inflation lumen. The catheter has a working length of 36.5 cm and is closed-ended with two side ports. The SPECTRUM™ Silicone Foley Catheter is impregnated with an antimicrobial combination of minocycline and rifampin which may

reduce the risk of gram positive bacterial colonization of the catheter and catheter-related bacteriuria during use. Based on HPLC analysis, the average amount of minocycline on the catheter is 25.2 mg (690μg/cm), and the average amount of rifampin on the catheter is 13.3 mg (363μg/cm).

Substantial Equivalence:

The SPECTRUM™ Silicone Foley Catheter is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510(k) substantial equivalency, and has undergone testing to support substantial equivalence. The substantially equivalent determination under the Federal Food, Drug, and Cosmetic Act is not intended to have any bearing whatsoever on the resolution of patent infringement suits or other patent matters.

The device will be manufactured according to specified process controls, undergoing processing, sterilization and packaging procedures similar to predicate devices currently manufactured and marketed by Cook Urological, Incorporated and Cook OB/GYN™.

Testing and Test Results

The SPECTRUM™ Silicone Foley Catheter has undergone biocompatibility testing (Cytotoxicity, USP Systemic Toxicity, USP Intracutaneous Toxicity, Urinary Bladder Irritation, USP Muscle Implantation with Histopathology, and Sensitization), performance testing consistent with *ASTM F 623-89 Standard Performance Specifications for Foley Catheter*, HPLC analysis, zone of inhibition testing, and clinical evaluation. Results of this testing showed the device to meet applicable test requirements and provide reasonable assurance of device performance for its intended use.

In Vitro Studies

In vitro zone of inhibition (ZI) studies have shown that the SPECTRUM™ Foley Catheter has inhibitory activity against indicator bacterial isolates (previously frozen isolates). ZI testing of segments of the SPECTRUM™ Foley Catheter after clinical use also demonstrated *in vitro* antimicrobial activity against tested urinary pathogens.

Clinical Studies

The SPECTRUM™ Foley Catheter was evaluated in two separate clinical studies, one involving placement of 30 SPECTRUM™ Foley Catheters (18 Fr, 36.5 cm in length) to evaluate antimicrobial activity and durability, and one prospective randomized multicenter study in which 141 radical prostatectomy patients were enrolled to evaluate efficacy of the SPECTRUM™ Foley in reducing bacteriuria.

To evaluate antimicrobial activity and durability, 30 SPECTRUM™ Foley Catheters were placed at different times in 12 spinal cord-injured patients who required the insertion of a

Foley catheter during hospitalization. The catheters were removed in six groups of five catheters each at days 3, 7, 10, 14, 17 or 21. At each interval, ZI testing was performed against clinical isolates of ten urinary pathogens. Results demonstrated that the SPECTRUM™ Silicone Foley Catheter provided broad spectrum *in vitro* antimicrobial activity against the tested urinary pathogens, with the inhibitory activity lasting at least two weeks after insertion. Using HPLC analysis, blood and urine samples obtained from patients receiving the SPECTRUM™ Silicone Foley Catheter showed no detectable systemic or urinary levels of minocycline or rifampin.

To evaluate efficacy of the SPECTRUM™ Foley Catheter in reducing bacteriuria, a prospective, randomized, multicenter clinical trial of patients undergoing radical prostatectomy was conducted in which 141 patients were enrolled to receive intraoperatively either a 20 Fr SPECTRUM™ Silicone Foley Catheter or standard non-coated silicone Foley catheter (control) to remain in place for 14 days. Urine cultures were obtained at approximately 3, 7 and 14 days after catheter insertion for evaluation of bacteriuria (defined as growth of organism(s) in urine at a concentration of $\geq 10^4$ CFU/ml). Of the 124 patients available for follow-up, 56 received the SPECTRUM™ Silicone Foley Catheter and 68 received the control catheter. Results showed that patients receiving the SPECTRUM™ Foley Catheter had significantly lower rates of bacteriuria than those receiving the control catheter at day 7 (15.2% versus 39.7%) and at day 14 (58.5% versus 83.5%). By day 14, patients having received the SPECTRUM™ Foley Catheter showed significantly lower rates of gram-positive bacteriuria versus the control catheter (7.1% versus 38.2%), but had similar rates of gram-negative bacteriuria (46.4% versus 47.1%) and candiduria (3.6% versus 2.9%). Bacteriuria in both groups of patients was caused by a similar variety of organisms, with the *Enterococcus* species being the most common gram-positive bacterium and the *Enterobacter* species being the most common gram-negative bacterium.. Symptomatic UTI (patient presenting clinical manifestations such as bladder spasms, fever/chills, urethral discharge, and/or bladder discomfort) was diagnosed by the health care provider in six (8.8%) of the 68 patients who received the non-coated control catheter as compared to one (1.8%) of the 56 patients who received the SPECTRUM™ Silicone Foley Catheter, but this trend did not reach statistical significance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2000

Cook Urological, Inc.
c/o Ms. Merry Lee Bain
MED Institute, Inc.
1400 Cumberland Avenue
West Lafayette, IN 47906

Re: K000251
SPECTRUM™ Silicone Foley Catheter
Dated: June 1, 2000
Received: June 2, 2000
Regulatory Class: II
21 CFR §876.5130/Procode: 78 MJC and EZL

Dear Ms. Bain:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K000251

Device Name: SPECTRUM™ Silicone Foley Catheter

Indications For Use:

The SPECTRUM™ Silicone Foley Catheter is a urological catheter indicated for use in urinary tract drainage or urine collection. Urinary tract access is generally accomplished by insertion of the catheter through the urethra and into the bladder, but may also be accomplished by suprapubic placement or by nephrostomy. The device will be supplied sterile and is intended for one-time use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000251